Message

From: Segall, Martha [Segall.Martha@epa.gov]
Sent: 9/13/2019 1:37:55 PM
To: Vizard, Elizabeth [Vizard.Elizabeth@epa.gov]
CC: Dombrowski, John [Dombrowski.John@epa.gov]
Subject: Fwd: GLP issue - Vietnam

Liz,

Ex. 5 Deliberative Process (DP)

Sent from my iPhone

Begin forwarded message:

> **From:** Ray McAllister <RMcAllister@croplifeamerica.org>
> **Date:** September 13, 2019 at 8:54:26 AM EDT
> **To:** "Vizard, Elizabeth" <Vizard.Elizabeth@epa.gov>
> **Cc:** "Dombrowski.john@Epa.gov" <Dombrowski.john@Epa.gov>, "Segall.martha@Epa.gov" <Segall.martha@Epa.gov>
> **Subject: FW: GLP issue - Vietnam**
>
> Liz:
>
> Rather than waiting longer for translations of Vietnamese documents and statements, I want to share this information with you now.
>
> At least four companies have recently had product registration applications held up by Vietnam because of lack of GLP certificates in the lab reports for acute tox studies from US labs. I assume there may be more companies affected. Because of this, product approvals are delayed, and the situation is urgent. Companies have already submitted the following documentation without success:
>
> - GLP certification guidelines and procedures
> - EPA letter to the individual lab following GLP inspection
> - EPA 40 CFR Part 160 – FIFRA GLP standards
> - EPA 40 CFR Part 792 – TSCA GLP standards
> - US FDA 21 CFR Part 58 – FDA GLP standards for non-clinical lab
> - Recent letters from Francis Liem on EPA letterhead to Vietnamese officials regarding specific laboratories and studies
>
> We are hopeful that a general explanation from EPA ("... to whom it may concern ...") of the following concepts might be convincing:
>
> - EPA subscribes to the OECD Mutual Acceptance of Data guidelines and protocols [details]
> - EPA verifies compliance of individual studies by requiring statement of study director with each report;
> - EPA periodically audits specific studies and labs to confirm compliance;
> - EPA provides letters upon request detailing the GLP audit history of a laboratory;
> - EPA does not issue certificates of compliance because ...

We are contemplating enlisting the assistance of the US Foreign Agricultural Service and in-country personnel of the US Embassy in Hanoi to help negotiate what would can be provided, and what would be acceptable.

If these steps are not successful, companies may be forced to conduct studies in Europe, depriving US laboratories of the business, in order to support registrations in Vietnam (and perhaps other countries).

Ray S. McAllister, Ph.D.
Senior Director, Regulatory Policy
CropLife America
202-872-3874 (office)
202-577-6657 (mobile)
ray@croplife.us

From: Vizard, Elizabeth <Vizard.Elizabeth@epa.gov>
Sent: Monday, September 9, 2019 9:49 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: RE: GLP issue - Vietnam

Good morning Ray-

Just touching base to see if you received the correspondence from Vietnam. If the problem is with GLP studies that are also in EPA's records we can specifically mention the studies in our response. Also, we can check the lab's inspection history if they provide the name, and address.

Elizabeth Vizard
Deputy Division Director, Acting
Monitoring, Assistance & Media Programs Division
Office of Compliance
202-564-5940

From: Ray McAllister <RMcAllister@croplifeamerica.org>
Sent: Thursday, August 29, 2019 10:03 AM
To: Vizard, Elizabeth <Vizard.Elizabeth@epa.gov>
Subject: RE: GLP issue - Vietnam

I've reached out to my colleagues in CropLife Asia for additional details, including any correspondence from PPD in Hanoi. I'll let you know as soon as I hear something. Thanks for the prompt reply.

Ray S. McAllister, Ph.D.
Senior Director, Regulatory Policy
CropLife America
202-872-3874 (office)
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ray@croplife.us

From: Vizard, Elizabeth <Vizard.Elizabeth@epa.gov>
Sent: Wednesday, August 28, 2019 11:07 AM
To: Ray McAllister <RMcAllister@croplifeamerica.org>
Subject: FW: GLP issue - Vietnam

Hi Ray-

Martha has shared your concern with me for resolution. Can you share with me any correspondence from Vietnam so I can work with the team here on a response. Info regarding the urgency/timeline will be helpful as well.

Elizabeth Vizard
Deputy Division Director, Acting
Monitoring, Assistance & Media Programs Division
Office of Compliance
202-564-5940

From: Segall, Martha <Segall.Martha@epa.gov>
Sent: Wednesday, August 28, 2019 10:23 AM
To: Vizard, Elizabeth <Vizard.Elizabeth@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>
Cc: Duffy, Rick <Duffy.Rick@epa.gov>; Liem, Francisca <Liem.Francisca@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>
Subject: FW: GLP issue - Vietnam

Liz, can you take the lead on this.

Thanks,

Martha

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Martha Segall
Director (Acting)
Monitoring, Assistance, and Media Programs Division
Office of Compliance/OECA
U.S. EPA
ph: (202) 564-0723

From: Ray McAllister <RMcAllister@croplifeamerica.org>
Sent: Wednesday, August 28, 2019 10:11 AM
To: Segall, Martha <Segall.Martha@epa.gov>
Cc: Liem, Francisca <Liem.Francisca@epa.gov>; Dombrowski, John <Dombrowski.John@epa.gov>
Subject: GLP issue - Vietnam

Martha:

We are running into problems in Vietnam, where the national pesticide regulatory authority (PPD Hanoi) is not accepting GLP studies conducted in the US because the individual study reports do not include a GLP compliance certificate for the lab where the study was conducted. Other countries routinely provide such certificates, so the omission is conspicuous by its absence for US studies. This issue raises its head from time to time.

I suspect this has come up multiple times. Does EPA have a prepared statement for regulatory authorities in other countries that explains –

- the US approach to GLP compliance and enforcement;
- how it conforms to OECD/GLP/MAD principles;
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- why compliance certificates are not issued; and
- how national regulatory authorities can be assured of GLP compliance by US labs and studies?

This particular problem is rather urgent. I would appreciate a prompt reply.

Ray S. McAllister, Ph.D.
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